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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------------|-------------|----------------------|---------------------|------------------|
| 09/909,207 | 07/19/2001 | Eric De Buyl | GC450-US-D1 | 1260 |
| 5100 | 7590 | 11/03/2003 | EXAMINER | |
| GENENCOR INTERNATIONAL, INC. | | | WILDER, CYNTHIA B | |
| ATTENTION: LEGAL DEPARTMENT | | | ART UNIT | PAPER NUMBER |
| 925 PAGE MILL ROAD | | | 1637 | 72 |
| PALO ALTO, CA 94304 | | | | |

DATE MAILED: 11/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/909,207 | DE BUYL ET AL. | |
| | Examiner | Art Unit | |
| | Cynthia B. Wilder, Ph.D. | 1637 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 11 August 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 7-18 and 25-35 is/are pending in the application.
- 4a) Of the above claim(s) 9,10 and 33 is/are withdrawn from consideration.
- 5) Claim(s) 11-18,25-30,32,34 and 35 is/are allowed.
- 6) Claim(s) 7,8 and 31 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. 08/470,953.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's preliminary amendment filed in Papers Nos. 6 and 7 is acknowledged and has been entered. Claims 1-6 and 19-24 have been canceled. Claims 31-35 have been added. Claims 7-18 and 25-35 are pending.
2. Applicant's preliminary amendment filed January 7, 2002 in Paper No. 8 is acknowledged. However, the preliminary amendment was only entered in part. Specifically, the amendment to the specification was not entered because Applicant did not specify page and line of entry.

Election/Restrictions

3. Applicant's election of SEQ ID NO: 1 corresponding claims 7, 8, 11-18, 25-32, 34 and 35 in Paper No. 11 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 9, 10, and 33 have been withdrawn from consideration as being drawn to a non-elected.

Priority

4. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 08/470,953, filed on June 6, 1995. .

Objections

5. Claim 31 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the

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claim(s) in independent form. Claim 31 is objected to because it does not further limit claim 7 from which it depends.

6. The specification is objected to because the word "invention" is misspelled at line 18.

Claim Rejections - 35 USC § 112 First Paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim is drawn to "an isolated and purified culture of Bacillus sp. 720/1(LMG P-14798) and culture derived or mutated from this culture". The recitation of "cultures derived from or mutated from said isolated cultured" encompasses a large genus of cultures not adequately described or disclosed. The specification teaches at page 6, that the invention relates to the identification and provision of a new, isolated and purified aerobic bacterium producing xylanase. The specification teaches that this strain bacterium belongs to the genus Bacillus and said Bacillus is Bacillus sp. Strain 720/1 or a derivative or mutant of this strain. The specification further teaches that derivatives of this strain are understood to mean any naturally modified bacterium. The specification however fails to adequately describe or disclose the large number

derivatives, variants and/or mutant cultures encompass by the claim as written. Likewise the specification fails to describe or disclose whether any derivatives, variants or mutants cultures as encompass by claim are functional in producing xylanase as set forth in the claim. As set forth by the Court in *Vas Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, the written description must convey to one of skill in the art "with reasonable clarity" that as of the filing date applicant was in possession of the claimed invention. Absent a written description disclosing a representative number of the species of the claimed invention of claim 7, the specification fails to show that applicant was, in fact, "in possession of the claimed invention" at the time the application for patent was filed.

9. Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 8 is drawn to a "an isolated DNA molecule comprising the nucleotide sequence illustrated in SEQ ID NO: 1 which codes for the mature xylanase of *Bacillus* sp. 720/1 (LMG P-14798) or a modified sequence derived from this sequence". The recitation of "a modified sequence derived from this sequence" encompasses a large genus of nucleic acid sequences not adequately described or disclosed. The specification as page 7 teaches that a "modified sequences derived from the DNA molecule is understood to mean any DNA molecule obtained by modification of one or more nucleotides of the gene which codes for the xylanase of the invention". The specification further teaches that the "modified sequence" is at least 70% identical or 80% identical and most preferably 90% to the sequence of SEQ ID NO: 1 which codes for the mature

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xylanase of *Bacillus* sp. 720/1 (LMG P-14798). The specification however fails to describe the numerous substitutions, insertion, deletions, nonsense, truncation or frameshift mutations encompassed by the recitation of "modified sequence derived from...". Likewise the specification does not disclose or describe wherein any modified sequence derived therefrom is capable of producing xylanase in any form. More specifically, there is no indication from the specification that any modified sequence derived therefrom is functional. Each of the claimed inventions is a genus for which a representative number of species for each genus must be disclosed to meet the written description requirement of 112, first paragraph. As set forth by the Court in *Vas Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, the written description must convey to one of skill in the art "with reasonable clarity" that as of the filing date applicant was in possession of the claimed invention. Absent a written description disclosing a representative number of the species of the claimed invention of claim 8, the specification fails to show that applicant was, in fact, "in possession of the claimed invention" at the time the application for patent was filed.

Conclusion

9. Claims 7, 8 and 31 are rejected. Claims 11-18, 25-30, 32, 34 and 35 contain allowable subject matter because the prior art does not teach an isolated DNA molecule comprising the nucleotide sequence of SEQ ID NO: 1 which codes for the mature xylanase of *Bacillus* sp. 720/1 (LMG P-14798), expression vectors and transformed strains comprising said DNA molecule. Likewise, the prior art does not teach a promoter sequence comprising SEQ ID NO: 26 wherein said promoter sequence is derived from the gene which codes for *Bacillus pumilus* PRL B12 xylanase or a presequence comprising the sequence of SEQ ID NO: 27 which codes for the

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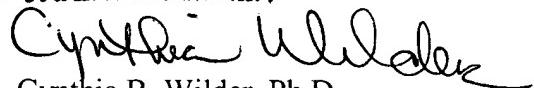
signal peptide of *Bacillus pumilus* PRL B12 xylanase and expression system comprising such promoter and/or presequence. No motivation could be found in the prior art for the limitations of the claims recited above. Accordingly, an obviousness rejection could not be made.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (703) 305-1680. The examiner can normally be reached on Monday through Thursday from 9:30 am to 6:30 pm and on Friday from 9:30 am to 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The official fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308 0196.

CYNTHIA WILDER
PATENT EXAMINER


Cynthia B. Wilder, Ph.D.
Examiner
Art Unit 1637

October 30, 2003